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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,294	02/28/2002	Loretta Nielsen	016930-003712US	3210

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EXAMINER	
HAMA, JOANNE	

ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/086,294	NIELSEN ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,10-22,25-28,30-32,34-40 and 78-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *79* is/are allowed.

6)☒ Claim(s) *1,3-5,10-22,25-28,30-32,34-40,78 and 80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant filed a response to the Non-Final Action of March 26, 2007 on June 26, 2007. Claims 2, 6-9, 23, 24, 29, 33, 41-77 are cancelled. Claims 35, 79, 80 are amended.

Claims 1, 3-5, 10-22, 25-28, 30-32, 34-40, 78-80 are under consideration

Withdrawn Objection

Claim Objection

Applicant's arguments, see page 7 of Applicant's response, filed June 26, 2007, with respect to the objection of claim 79 have been fully considered and are persuasive. Claim 79 has been amended and does not recite protein. The objection of claim 79 has been withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 80 remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

1) an *in vivo* method for reducing the size of a tumor in a mammal comprising mammalian cancer cells deficient in functional p53, said method comprising directly contacting cancer cells with an adenoviral vector comprising a nucleic acid encoding p53, and also contacting said cells with a microtubule affecting agent, wherein the microtubule affecting agent

comprises a taxane, such that growth of said cancer cells is reduced and/or said cancer cells undergo apoptosis,

does not reasonably provide enablement for

1) an *in vivo* method of treating mammalian cancer cells deficient in functional p53, wherein said method comprises contacting cancer cells with an adenoviral vector comprising a nucleic acid encoding p53, wherein said vector is administered directly, and contacting said cells with a taxane, such that one or more disease characteristic of the cells is ameliorated, wherein the mammalian cancer cells are human head and neck, ovarian, prostate, or mammary cancer cells.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons of record, December 5, 2005 and July 5, 2006, and March 26, 2007.

Applicant's arguments filed June 26, 2007 have been fully considered but they are not persuasive.

Applicant indicates that claim 80 has been amended such that the cancer cells are tumor cells and thus, the rejection of the claims has been overcome. In response, this is not persuasive because tumor cells are not confined to the tumor. They can metastasize from the tumor and form new sites of tumors. As such, the rejection as it applies to this issue remains.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments filed June 27, 2007 have been fully considered but they are not persuasive.

Applicant indicates that claim 30 has been amended to address the differences in scope of claim 1 (direct injection into a tumor) and claim 30 (intraperitoneal administration). However, claim 30 has not been amended. As such, the rejection to this claim remains.

The rejection of claim 33 is withdrawn as the claim is cancelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3, 10, 18-22, 25-28, 31, 32, 78, 80 remain rejected under 35 U.S.C. 102(e) as being anticipated by Tocque, US Patent 6,262,032, patented July 17, 2001, as evidenced by Brown et al., 1991, Journal of Clinical Oncology, 9: 1261-1267, for reasons of record, March 26, 2007.

Applicant's arguments filed June 26, 2007 have been fully considered but they are not persuasive.

Applicant indicates that the 102(e) date of Tocque is July 17, 1997 and that the instant application claims priority to US Provisional Applications 60/038,065 and 60/047,834, filed February 18, 1997 and May 28, 1997, respectively. Because the instant claims are supported by these provisional applications, Tocque is not a proper 102(e) date (Applicant's response, page 8). In response, this is not persuasive. In looking at both provisional applications, neither application provides support for in vivo treatment of tumors using the adenoviral vector comprising a nucleic acid sequence encoding p53 and a taxane. There is in vitro support (60/038,065, Example 6; 60/047,834, Example 6), which overcomes the rejection of claim 79. However, this is not in vivo support. As such, the priority date of the instant application is February 17, 1998.

As such, rejection of claims 1, 3, 10, 18-22, 25-28, 31, 32, 78, 80 is maintained. The rejection of claim 79 is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 10-17, 34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gregory, US Patent 5,932,210, patented August 3, 1999, for reasons of record, July 5, 2006 and March 26, 2007.

Applicant's arguments filed June 26, 2007 have been fully considered but they are not persuasive.

Applicant indicates that Tocque is not a proper 102(e) reference (Applicant's response, page 8, under "First Rejection under 35 USC 103"). In response, this is not persuasive. Tocque is a proper 102(e) reference, see above.

Applicant indicates that Gregory and the instant application are both owned or subject to an obligation of assignment to Canji, Inc., and Gregory was filed subsequent to both of the provisional applications to which the instant application claims priority. Thus, Gregory is not proper 103 reference (Applicant's response, page 8, under "First Rejection under 35 USC 103"). In response, this is not persuasive. With regard to Applicant indicating that Gregory and the instant application are both owned or subject to an obligation of assignment to Canji, Inc., the statement does not indicate that the subject matter and the claimed invention were, "at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person." As such, Applicant's statement does not overcome this aspect of the 103 rejection. With regard to Applicant indicating that Gregory was filed subsequent to both of the provisional applications of the instant application, Gregory is a continuation of

application 08/328,637, filed October 25, 1994, which means that Gregory has priority at least up to this date.

Thus, the rejection as it applies to this issue remains.

Applicant indicates that the second 103 rejection appears to be the same as that of the first 103 rejection (Applicant's response, pages 8-9). In response, Applicant is correct and the claims that were rejected in the second 103 rejection have been combined in the rejection above.

Claims 1, 4, 5 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tocque in view of Roth et al., 1997, Journal of the National Cancer Institute, 89: 21-39 and Shea, 1997, Cancer Chemotherapy and Pharmacology, 40, Suppl: S74-S78 for reasons of record, March 26, 2007.

Applicant's arguments filed June 26, 2007 have been fully considered but they are not persuasive.

Applicant indicates that Tocque is not a proper 102(e) reference. In response, as discussed above, the instant Application does not have priority to February 18, 1997 and May 28, 1997 because neither provisional application provides any guidance to using the adenoviral vector comprising a nucleic acid sequence encoding p53 and a taxane in vivo.

With regard to Applicant asking for clarification as to why claim 1 was included in the rejection (Applicant's response, page 9), claim 1 is an independent claim upon which claims 4 and 5 depend. As such, because claims 4 and 5 depend on claim 1 for their limitations, it was included in the rejection.

Conclusion

Claim 79 is considered allowable at this time.

1, 3-5, 10-22, 25-28, 30-32, 34-40, 78, 80 are not allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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